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Administrative Practices Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules

November 1980

Prepared by the
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REPORT OF THE

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YEAR 1880

ADMINISTRATIVE PRACTICES SUPPLEMENT
POLICIES AND ADMINISTRATIVE PROCEDURES FOR
RECOMBINANT DNA RESEARCH SUBJECT TO THE NIH GUIDELINES

This Supplement to the NIH Guidelines for Research Involving Recombinant DNA Molecules applies only to recombinant DNA research subject to the Guidelines as revised in November 1980 and thereafter by the Director, NIH (See Section I-E of the Guidelines for exempt experiments). This Supplement supersedes the Supplement dated April 1980. In cases in which the instructions in this Supplement differ from those in Public Health Service grant application kits, the instructions in this Supplement take precedence.

I. INSTITUTIONAL BIOSAFETY COMMITTEE

Each Institution involved in the conduct of recombinant DNA research subject to the Guidelines must have a standing Institutional Biosafety Committee (IBC). Requirements and recommendations for the composition of such a committee are discussed under Part IV of the Guidelines, which also discusses the roles and responsibilities of Principal Investigators (PIs) and Institutions.

A roster of the members of the IBC shall be submitted to the Office of Recombinant DNA Activities (ORDA). This must include the names, addresses, occupations, qualifications, and curricula vitae of the chairperson and members of the committee. The information should be addressed to:

Office of Recombinant DNA Activities
National Institutes of Health
Building 31, Room 4A52
Bethesda, Maryland 20205

The membership of IBCs is subject to review by ORDA for compliance with requirements stated in the Guidelines. The Institution shall report promptly to ORDA any changes in this information.

ORDA will assist in the formation of an Area Biosafety Committee (ABC) when appropriate. Such a committee, composed of members from the Institution and other organizations beyond its own staff, may be necessary as an alternative to an IBC when additional expertise from outside a given Institution is necessary for the IBC to fulfill its functions.

II. REGISTRATION OF EXPERIMENTS

Recombinant DNA research subject to the Guidelines must be registered with the IBC in accordance with the requirements stated in Part III of the Guidelines.

IBCs are required to keep records of recombinant DNA research conducted at their institution. IBCs should maintain a record of the frequency of disagreement between the principal investigator and the IBC in the classification of experiments.

III. CHECK BOX AND NOTATION ON APPLICATIONS FOR RESEARCH, TRAINING, AND RESOURCE GRANTS

For competing and noncompeting applications (all series) involving recombinant DNA research subject to the Guidelines, the box "YES" under "RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES" is to be checked. No additional information for registration of the recombinant DNA aspects of the proposal need be submitted to NIH.

If the application form does not have the above-mentioned check box, the following statement should be typed at the bottom of the face page of the application:

RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES

IV. ACTIVITIES REQUIRING PRIOR NIH APPROVAL

A. Containment Levels Not Specified by the Guidelines. The setting of containment levels for projects for which containment levels are not explicitly specified by the NIH Guidelines or NIH will require review by NIH, usually involving recommendation by the Recombinant DNA Advisory Committee (RAC). Hence, investigators are urged to provide to ORDA, in writing, full information on the proposed experiments prior to submission of a registration document to the IBC.

B. Requests for Exceptions and Exemptions. Requests for an exception to a prohibition or an exemption from the Guidelines must be submitted to ORDA, with adequate documentation. Because the handling of requests for exceptions and exemptions will involve review by the RAC with provision for public comment, investigators are urged to discuss the proposal with ORDA before submitting a formal request. Decisions on requests for exceptions or exemptions will be published in the Federal Register and the Recombinant DNA Technical Bulletin.

V. POLICY AND PROCEDURES FOR RECOMBINANT DNA RESEARCH SUPPORTED BY NIH AND CONDUCTED IN FOREIGN COUNTRIES

A. Requirements Regarding Countries That Have Adopted Guidelines. Many countries in which NIH-supported recombinant DNA research may be conducted have adopted guidelines for this research which are either comparable to or based on principles similar to those of the NIH Guidelines. Also, many countries have organizations and procedures to review and register recombinant DNA research. If such comparable guidelines and procedures exist, then review and approval by the appropriate body will, in general, be accepted as assurance that the research will be conducted in a responsible manner. Applicants should provide such assurance of compliance in the application. NIH reserves the right, however, to withhold funding if the safety practices to be employed are not reasonably consistent with the NIH Guidelines.

B. Requirements Regarding Countries That Have Not Adopted Guidelines.

NIH funds may not be used for the conduct of recombinant DNA research in a country that has not adopted national guidelines unless there is assurance that the research will be conducted in compliance with the NIH Guidelines.

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